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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,099	01/24/2002	Fu-Zon Chung	A0000247-01-DRK	1420
28880	7590	07/27/2004	EXAMINER	
WARNER-LAMBERT COMPANY			LANDSMAN, ROBERT S	
2800 PLYMOUTH RD			ART UNIT	
ANN ARBOR, MI 48105			PAPER NUMBER	

1647

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,099

Applicant(s)

CHUNG ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,10 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 10 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/24/02 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

- A. The Amendment dated 5/10/04 has been entered into the record.
- B. Claims 1-3, 5, 6, 10, 16, 17 and 19 were pending in the application. Claims 16 and 17 have been canceled and new claims 20-23 have been added in the Amendment dated 5/10/04. Therefore, claims 1-3, 5, 6, 10 and 19-23 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The specification is objected to since, in the "Brief Description of the Drawings," "Figure 3" should recite "Figures 3A and 3B."
- B. The specification remains objected for the reasons cited on the Draftsperson's Drawing Review Sheet dated 3/27/03 (Paper No. 8). Applicants' request that these objections be deferred until allowance has been accepted.

3. Claim Objections

- A. The objection to claim 1 has been withdrawn in view of Applicants' amendment to the claim to recite "an NK receptor." Though not objected to in the previous Action, Applicants have also amended claim 19 to recite "an NK1 receptor."
- B. Claims 1-3, 5, 6, 10 and 19-23 are objected to since it is believed that there is a typographical error in claims 1, 19 and 20 and that the term "reported" in part (e) should be "reporter." Claims 2, 3, 5, 6, 10 and 21-23 are also objected to since they depend from claims 1, 19 or 20.
- C. Claims 1-3, 5, 6, 10 and 19-23 are objected to since the syntax of part (a) of claims 1, 19 and 20 could be improved by replacing the phrase "in response to Erk-2 activation" with, for example, "which responds to Erk-2 activation." Claims 2, 3, 5, 6 and 10 are objected to since they depend from claims 1, 19, or 20.

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. The rejection of claims 1-3, 5, 6, 10 and 19 under 35 USC 112, first paragraph, regarding how it can be concluded that simply determining the effect of a test compound on Erk-2 expression is indicative of a compound having gabapentinoid activity, has been withdrawn in view of Applicants' amendments to claims 1 and 19 to limit the scope of test compounds to those which binds to the $\alpha 2\delta$ subunit of a calcium channel as well as reciting the functional limitation of step (g). However, this rejection will be reinstated if Applicants are not able to overcome the below rejection under 35 USC 112, first paragraph, regarding "new matter."

B. The rejection of claims 1-3, 5, 6, 10, and 19 under 35 USC 112, first paragraph, regarding the conflict between claims 1 and 16 has been withdrawn in view of Applicants' cancellation of claim 16 as well as Applicants' arguments that page 15, lines 16-20 of the specification clearly demonstrates that Erk-2 phosphorylation (i.e activation) can be determined in cells which do not overexpress the NK receptor.

5. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. Claims 1-3, 5, 6, 10 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have added the limitations "that binds to the $\alpha 2\delta$ subunit of a calcium channel" into claims 1 and 19 and have added chemical structures and numerous analogs in their addition of new claim 20. Applicants argue that the incorporation of WO 99/21824 (referenced on page 11, lines 1-3 of the specification) provide support for these limitations. Applicants further argue that the reference by Gee et al. (JBC 1996) further supports Applicants' added limitations. First, while Gee et al. may demonstrate that the use of the $\alpha 2\delta$ subunit of a calcium channel is *enabled*, it is still new matter since this limitation is not found in the specification or claims as originally filed.

Furthermore, with regard to the "essential material" provided in the new claim limitations (i.e. "that binds to the $\alpha 2\delta$ subunit of a calcium channel" and the chemical structures and analogs) and Applicants' reliance on WO 99/21824 for support of these limitations, MPEP 608.01(p) states "an application for a patent when filed may incorporate "essential material" by reference to (1) a U.S. patent, (2) a U.S. patent application publication, or (3) a pending U.S. application, subject to the conditions set forth below. "Essential material" is defined as "that which is necessary to (1) describe the claimed

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invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode (35 U.S.C. 112). In any application which is to issue as a U.S. patent, essential material may not be incorporated by reference to (1) patents or applications published by foreign countries or a regional patent office, (2) non-patent publications, (3) a U.S. patent or application which itself incorporates 'essential material' by reference, or (4) a foreign application."

MPEP 608.01(p) further states "mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found." Therefore, the limitations which recite "that binds to the $\alpha 2\delta$ subunit of a calcium channel" into claims 1 and 19 and the added chemical structures and numerous analogs in new claim 20 are considered **new matter**.

6. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 1-3, 5, 6, 10 and 19 under 35 USC 112, second paragraph, regarding the lack of a conclusion step, has been withdrawn in view of Applicants' amendments to claims 1 and 19 to recite the functional limitation of step (g).

B. The rejection of claims 1-3, 5, 6, 10 and 19 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendment to the claims to recite "test compound." No rejection is being made over the recitation of "target compound" as recited in claim 20, since, as argued by Applicants, the metes and bounds of this term is defined by use of the specific structures in the claim.

C. The rejection of claims 1-3, 5, 10 and 19 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendment to the claims to recite a functional limitation in step (g) in claims 1 and 19. It is now clear what the purpose is of "at least two groups," and "a plurality of groups." Claim 6 was inadvertently omitted from this rejection. However, this issue is moot since the rejection has been withdrawn.

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7. Conclusion

A. No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Advisory information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
July 23, 2004


ROBERT LANDSMAN
PATENT EXAMINER